6 September 2016
EMA/CVMP/602377/2016
Committee for Medicinal Products for Veterinary Use (CVMP)

Committee for Medicinal Products for Veterinary Use

Minutes of the 12-14 July 2016 meeting

Chair: D. Murphy – Vice-chair: H. Jukes

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

i. Adoption of the Agenda

The Committee adopted the agenda with no modifications.

ii. CVMP delegates' list of intended participation and identified interests

The attendance list was completed and interests were identified for the July 2016 meeting. In accordance with the Agency's policy and procedure on the handling of declarations of interests, participants in this meeting were asked to declare any interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests). Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of the meeting (see Annex I). All decisions taken at this meeting were made in presence of a quorum of members i.e. 22 or more members were present in the room. It was noted that 17 members were needed for an absolute majority.

iii. Declaration of contacts between members and companies with regard to points on the agenda

Information relating to declared contacts between members and companies with regard to points on the agenda cannot be released at the present time as it is deemed to be commercially confidential.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

iv. Adoption of the minutes of the previous meeting

The minutes of the June 2016 meeting were adopted with no amendments.

v. Topics for rapporteur's meetings, break-out sessions and oral explanations

Information relating to briefing meetings taking place with applicants cannot be released at the present time as it is deemed to be commercially confidential.

1. ESTABLISHMENT OF MAXIMUM RESIDUE LIMITS

1.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of final maximum residue limits for **aluminium salicylate, basic** (EMEA/V/MRL/003298/MODF/0004) in tissues of bovine, caprine, *Equidae* and rabbits, and in milk for bovine, caprine and *Equidae*, further to the establishment of provisional MRLs. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the comments from the EU Reference Laboratory, a peer review report and the summary of opinion for publication.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion including the EPMAR and the CVMP assessment report recommending the establishment of MRLs in all ruminants except bovine for **gamithromycin** (EMEA/V/MRL/003158/EXTN/0003). The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted a peer review report and the summary of opinion for publication.

1.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

1.3 Lists of questions

- The Committee adopted the scientific overview and list of questions for the establishment of MRLs in honey for a substance (EMEA/V/MRL/003596/FULL/0002), following discussion of the rapporteur's assessment report, including the critique from the co-rapporteur, and two peer review reports.

1.4 Re-examination of CVMP opinions

- There were no items for discussion.

1.5 Other issues

- There were no items for discussion.

2. COMMUNITY MARKETING AUTHORISATIONS AND EXTENSIONS

2.1 Opinions

- The Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for **ERAVAC** (EMEA/V/C/004239/0000), recommending the granting of a marketing authorisation. The product is an inactivated vaccine for the active immunisation of fattening rabbits to reduce mortality against the Type 2 variant of rabbit haemorrhagic disease virus (RHDV2). The

Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. The Committee noted the summary of opinion for publication.

2.2 Oral explanations and lists of outstanding issues

- The Committee adopted the updated scientific overview including the list of outstanding issues, to be addressed in writing and at an oral explanation in November 2016, for a marketing authorisation application for a new vaccine for pigs (EMEA/V/C/003993/0000). The Committee also agreed comments on the draft product information and noted a peer review report and the comments received from CVMP members.

2.3 Lists of questions

- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for an extension application for **EQUIOXX** (EMEA/V/C/000142/X/0015), to add a new pharmaceutical form for horses. The Committee noted a peer review report and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new antiparasitic product for dogs (EMEA/V/C/004247/0000). The Committee noted two peer review reports and the comments received from CVMP members.
- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new product (EMEA/V/C/004376/0000) for psycholeptic use in dogs and cats.
- The Committee adopted the scientific overview including the list of questions, and agreed comments on the draft product information for a new product for disorders of the musculo-skeletal system in dogs (EMEA/V/C/004375/0000). The Committee noted two peer review reports and the comments received from CVMP members.

2.4 Re-examination of CVMP opinions

- The Committee adopted the list of questions to be addressed by the ad hoc expert group (AHEG) and endorsed the AHEG members for the re-examination of the negative CVMP opinion adopted for an extension application for **DRAXXIN** (EMEA/V/C/000077/X/0029), to include a new target species (sheep).

2.5 Other issues

- There were no items for discussion.

3. VARIATIONS TO COMMUNITY MARKETING AUTHORISATIONS

3.1 Opinions

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion, the CVMP assessment report and the product information for a type II variation for **Suvaxyn Circo+MH RTU** (EMEA/V/C/003924/II/0002), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a grouped worksharing type IB variation for **Comfortis** and **Trifexis** (EMEA/V/C/WS/0906/G), recommending the variation of the

marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **Vectormune ND** (EMEA/V/C/003829/II/0004), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.
- The Committee adopted by consensus (27 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for a type II variation for **BLUEVAC BTV8** (EMEA/V/C/000156/II/0007), recommending the variation of the marketing authorisation to implement quality changes. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP.

3.2 Oral explanations and lists of outstanding issues

- There were no items for discussion.

3.3 Lists of questions

- The Committee adopted the list of questions for a grouped type II variation for **Stronghold** (EMEA/V/C/000050/II/0055/G), concerning quality changes.

3.4 Re-examination of CVMP opinions

- There were no items for discussion.

3.5 Other issues

- The Committee agreed to a request from the MAH for a 3-month extension to the clock-stop for a type II variation for **Activyl Tick Plus** (EMEA/V/C/002234/II/0008), to add a new therapeutic indication, and adopted a revised timetable for the procedure.

4. REFERRALS AND RELATED PROCEDURES

4.1 Article 33 of Directive 2001/82/EC

- There were no items for discussion.

4.2 Article 34 of Directive 2001/82/EC

- The Committee agreed to the request from Elanco Animal Health for a 1-month extension to the clock-stop for the referral procedure for **Denagard 45% and associated names** (EMEA/V/A/114) and adopted a revised timetable for the procedure.
- The Committee considered the notification from Spain, for a referral procedure for **Girolan and its associated name Apralan** due to divergent decisions reached by the Member States resulting in differences in the product information. The Committee agreed to start a referral procedure (EMEA/V/A/122) under Article 34 and appointed C. Muñoz Madero as rapporteur and B. Urbain as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable.
- The Committee considered the notification from the European Commission, for a referral procedure for **Lincocin and its associated names** due to divergent decisions reached by Member States resulting in differences in the product information. The Committee agreed to start a referral procedure (EMEA/V/A/123) under Article 34 and appointed C. Muñoz Madero as

rapporteur and H. Jukes as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable.

4.3 Article 35 of Directive 2001/82/EC

- The Committee agreed to the request from Zoetis for a 2-month extension to the clock-stop for the referral procedure for **veterinary medicinal products containing moxidectin to be administered to cattle, sheep and horses** (EMEA/V/A/116), and adopted a revised timetable for the procedure.
- The Committee was informed of the letter from Laboratorios Hipra for the referral procedure for **veterinary medicinal products containing gentamicin presented as solutions for injection to be administered to cattle and pigs** (EMEA/V/A/117), concerning the exclusion of its products Gentamox and Gentipramox from the scope of the procedure. The Agency's response confirming the exclusion was also noted.
- The Committee considered the notification from Finland, for a referral procedure for **veterinary medicinal products containing tylosin that are administered parenterally and intended for the treatment of bovine mastitis caused by *Mycoplasma* spp** due to concerns related to the efficacy of tylosin in the treatment of bovine mastitis caused by *Mycoplasma* spp. The Committee agreed to start a referral procedure (EMEA/V/A/121) under Article 35 and appointed M. Nevalainen as rapporteur and A. Wachnik-Święcicka as co-rapporteur for the procedure. The Committee adopted the list of questions and the timetable.
- The Committee discussed the rapporteur's assessment report including the co-rapporteur's critique for the referral procedure for **all veterinary medicinal products containing zinc oxide to be administered orally to food producing species** (EMEA/V/A/118). The Committee adopted a list of outstanding issues for the applicants and marketing authorisation holders to address in writing, and the revised timetable for the procedure. The Committee noted three peer review reports and the comments made by CVMP members.

4.4 Article 45 of Regulation 726/2004

- Following the oral explanation from the marketing authorisation holder, CEVA Santé Animale, and discussion of the rapporteur's revised assessment report, the Committee adopted by consensus (24 members present of those eligible to vote) the CVMP opinion and the CVMP assessment report for the referral procedure for **Velactis** (EMEA/V/A/120). The Committee concluded that at present the overall benefit-risk balance for the product is considered unfavourable and recommended suspension of the marketing authorisation for Velactis until the underlying cause of the reported adverse events and associated risk factors are clearly elucidated and adequate risk management measures can be proposed to restore a positive benefit-risk balance. In addition, the CVMP recommended a recall of Velactis at all levels of the distribution chain (including veterinarian/user level) in the EU to prevent further exposure. The Norwegian CVMP member agreed with the above-mentioned recommendation of the CVMP. - *see also 5.5*.

4.5 Article 13 of Regulation (EC) No 1234/2008

- There were no items for discussion.

4.6 Article 30(3) of Regulation (EC) No 726/2004

- There were no items for discussion.

4.7 Other issues

- There were no items for discussion.

5. POST-AUTHORISATION ISSUES FOR COMMUNITY MARKETING AUTHORISATIONS (EXCLUDING VARIATIONS)

5.1 General issues

- There were no items for discussion.

5.2 Post-authorisation measures and annual reassessments

- The Committee adopted the rapporteur's assessment report on the data submitted concerning two conditions for **EVALON** (EMEA/V/C/004013/ANX/001-002).

5.3 Product anniversary list

- The Committee endorsed the product anniversary list for the period between 17.06.2016 – 14.07.2016:

Product	Period
Canigen L4 (EMEA/V/C/004079)	03/07/2015 – 02/07/2016
Circovac (EMEA/V/C/000114)	21/06/2015 – 20/06/2016
Convenia (EMEA/V/C/000098)	19/06/2015 – 18/06/2016
Equilis Prequenza (EMEA/V/C/000094)	08/07/2015 – 07/07/2016
Equilis Prequenza Te (EMEA/V/C/000095)	08/07/2015 – 07/07/2016
Equilis Te (EMEA/V/C/000093)	08/07/2015 – 07/07/2016
EQUIOXX (EMEA/V/C/000142)	25/06/2015 – 24/06/2016
ERYSENG (EMEA/V/C/002761)	04/07/2015 – 03/07/2016
ERYSENG PARVO (EMEA/V/C/002762)	08/07/2015 – 07/07/2016
Innovax-ILT (EMEA/V/C/003869)	03/07/2015 – 02/07/2016
LEUCOFELIGEN FeLV/RCP (EMEA/V/C/000143)	25/06/2015 – 24/06/2016
LEUCOGEN (EMEA/V/C/000144)	17/06/2015 – 16/06/2016
Melovem (EMEA/V/C/000152)	07/07/2015 – 06/07/2016
Posatex (EMEA/V/C/000122)	23/06/2015 – 22/06/2016
PRILACTONE (EMEA/V/C/000105)	20/06/2015 – 19/06/2016
ProZinc (EMEA/V/C/002634)	12/07/2015 – 11/07/2016
Reconcile (EMEA/V/C/000133)	08/07/2015 – 07/07/2016
Suprelorin (EMEA/V/C/000109)	10/07/2015 – 09/07/2016
Versican Plus DHPPi (EMEA/V/C/003679)	04/07/2015 – 03/07/2016
Versican Plus Pi (EMEA/V/C/003681)	04/07/2015 – 03/07/2016

5.4 Renewals

- There were no items for discussion.

5.5 Pharmacovigilance – PSURs and SARs

- The Committee discussed the signal detection findings from the rapporteur on the adverse event reports for **Velactis** (EMEA/V/C/003739). The rapporteur proposed to continue with 2-weekly signal detection and confirmed the need for the MAH to submit the first 6-monthly PSUR within 30 days (instead of 60 days) of the data lock point. – *see also 4.4*.
- The Committee adopted the CVMP assessment report of the PSUR for the period 01.04.2015 – 31.03.2016 for **COXEVAC** (EMEA/V/C/000155) with a recommendation to amend the product literature.
- The Committee adopted the following CVMP PSUR assessment reports concluding that no changes to the product literature or other regulatory actions were required for:

Product	Period
Dexdomitor (EMEA/V/C/000070)	01.03.2013 – 29.02.2016
NexGard (EMEA/V/C/002729)	01.09.2015 – 29.02.2016
Nobilis IB 4-91 (EMEA/V/C/000036)	01.10.2015 – 31.03.2016
Nobilis IB Primo QX (EMEA/V/C/002802)	01.10.2015 – 31.03.2016
Nobivac Bb (EMEA/V/C/000068)	01.04.2013 – 31.03.2016
Proteq West Nile (EMEA/V/C/002005)	01.03.2015 – 29.02.2016
Purevax Rabies (EMEA/V/C/002003)	01.03.2015 – 29.02.2016
Suprelorin (EMEA/V/C/000109)	01.02.2015 – 31.01.2016
Vectormune ND (EMEA/V/C/003829)	08.09.2015 – 31.03.2016
ZULVAC 1 Ovis (EMEA/V/C/002335)	01.03.2015 – 29.02.2016
ZULVAC 1+8 Ovis (EMEA/V/C/002251)	01.04.2015 – 31.03.2016

- The Committee endorsed the list of products and calendar for signal detection analysis.

5.6 Supervision and sanctions

Information relating to supervision and sanctions will not be published as it would be undermining the purpose of such inspections.

6. CO-OPERATION WITH OTHER EU OR INTERNATIONAL BODIES

6.1 VICH

- The Committee endorsed the draft EU comments on VICH GL22 on reproduction testing and inclusion of the extended one generation reproduction toxicity study. The comments will be forwarded to the Safety Expert Working Group.
- The Committee endorsed the draft VICH GL56 on studies to evaluate metabolism and residues kinetics of veterinary drugs in food producing species: study design recommendations for

residues studies in honey for establishing MRLs and withdrawal periods, for sign-off at step 2 of the VICH process.

- The Committee deferred the verbal report on the 33rd VICH Steering Committee meeting and the 7th Outreach Forum meeting held on 20-23 June 2016 in Brussels-Belgium to the September 2016 CVMP meeting.

6.2 Codex Alimentarius

Information relating to certain topics discussed under section 6.2 at this meeting cannot be released at the present time as it is deemed to be confidential.

6.3 Other EU bodies and international organisations

Information relating to certain topics discussed under section 6.3 at this meeting cannot be released at the present time as it is deemed to be confidential.

7. WORKING PARTIES AND SCIENTIFIC ADVISORY GROUPS

Information relating to certain topics discussed under section 7 at this meeting cannot be released at the present time as it is deemed to be confidential.

7.1 Scientific Advice Working Party (SAWP-V)

Information relating to SAWP-V procedures cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee received a verbal report from the chair of the SAWP-V on the meeting held on 12 July 2016, and noted the agenda of the meeting.

7.2 Quality Working Party (QWP)

- The Committee adopted the reflection paper on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances in marketing authorisation applications for veterinary medicinal products (EMA/CVMP/QWP/3629/2016) for a 3-month period of public consultation.

7.3 Safety Working Party (SWP-V)

- The Committee adopted the draft guideline on approach towards harmonisation of withdrawal periods (EMA/CVMP/SWP/735325/2012) for a 6-month period of public consultation.

7.4 Environmental Risk Assessment Working Party (ERAWP)

- The Committee adopted the revised question and answer document (EMA/CVMP/ERA/172074/2008) in support to the guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 (Phase I) and GL38 (Phase II).
- The Committee adopted the guideline on the higher tier testing of veterinary medicinal products to dung fauna (EMA/CVMP/ERA/409350/2010) for a 6-month period of public consultation.
- The Committee endorsed the proposal for training of assessors on environmental risk assessment to be held in October 2016.
- The Committee agreed to the proposal for the appointment of two additional working party experts (EMA/CVMP/ERA/475827/2016) with expertise on modelling, degradation of veterinary

medicinal products in the environment and knowledge on veterinary practice. A call for nominations will be circulated following the July CVMP meeting.

- The Committee received feedback from the workshop on the environmental risk assessment for veterinary medicinal products for use on aquaculture held on 22-23 June 2016.
- The Committee received a verbal report from the chair of the ERAWP on the meeting held on 21-22 June 2016 (EMA/CVMP/ERA/494783/2016).

7.5 Efficacy Working Party (EWP-V)

- The Committee deferred the verbal report from the chair of the EWP-V on the focus group meeting held on 13 June 2016 for the September 2016 CVMP meeting.
- The Committee adopted the concept paper for the revision of the guideline on anticoccidials for the therapy of coccidiosis in chickens, turkeys and geese (7AE15a Vol. 7) (EMA/CVMP/EWP/706095/2015) for a 3-month period of public consultation.
- The Committee adopted the revised guideline on the testing and evaluation of the efficacy of antiparasitic substances for the treatment and prevention of tick and flea infestations in dogs and cats (CVMP/EWP/005/2000-Rev.3) and overview of comments received (EMA/CVMP/EWP/495905/2015).

7.6 Antimicrobials Working Party (AWP)

- The Committee adopted the concept paper on revision of the current guideline on the SPC for the antimicrobial products (EMA/CVMP/AWP/161553/2016) for a 3-month period of public consultation.
- The Committee deferred the verbal report from the chair of the AWP on the meeting held on 25-26 May 2016 to the September 2016 CVMP meeting.

7.7 Immunologicals Working Party (IWP)

- The Committee deferred the verbal report from the chair of the IWP on the meeting held on 29-30 June 2016 to the September 2016 CVMP meeting.
- The Committee endorsed the proposal for assessors' training on efficacy of the immunological veterinary medicinal products and noted the draft training programme.

7.8 Pharmacovigilance Working Party (PhVWP-V)

- The Committee deferred the verbal report from the chair of the PhVWP-V on the meetings held on 24-25 May 2016 and on 5-6 July 2016 to the September 2016 CVMP meeting.
- The Committee deferred the verbal report on the surveillance workshop held on 25 May 2016 to the September 2016 CVMP meeting.
- The Committee adopted the question and answer document on expressing the frequency of adverse reactions within the product information (EMA/CVMP/PhWVP/150343/2016).

7.9 Novel therapy groups and related issues

- The Committee adopted the problem statement on stem cell-based products for veterinary use: specific questions on target animal safety (EMA/CVMP/ADVENT/193811/2016) for a 2-month period of public consultation.

- The Committee adopted the problem statement on stem cell-based products for veterinary use: specific questions on tumorigenicity (EMA/CVMP/ADVENT/207268/2016) for a 2-month period of public consultation.

7.10 Joint CVMP/CHMP AHEG on the application of the 3Rs (JEG-3Rs)

- The Committee adopted the report on the actions taken for the review and update of EMA guidelines to implement best practice with regard to 3Rs (replacement, reduction and refinement) in regulatory testing of medicinal products (EMA/CHMP/CVMP/JEG-3Rs/677407/2015) for a 3-month period of public consultation following its adoption by CHMP.
- The Committee adopted the draft guideline for individual laboratories for transfer of quality control methods validated in collaborative trials with a view to implementing 3Rs for a 6-month period of public consultation.

7.11 Other working party and scientific group issues

The following documents were circulated for information:

- Draft minutes of the SAWP-V meeting held on 14 June 2016;
- Final minutes of the QWP meeting held on 1–3 March 2016;
- Final minutes of the IWP meeting held on 11–12 February 2016.

8. OTHER SCIENTIFIC MATTERS

8.1 MRLs issues

Information on certain MRL related issues cannot be released at the present time as it is deemed to be confidential.

8.2 Environmental risk assessment

- There were no items for discussion.

8.3 Antimicrobial resistance

- The Committee adopted the updated advice of the Expert Advisory Group on Antimicrobial Resistance (AMEG) on the use of colistin products in animals within the European Union, and the overview of comments received.
- The Committee deferred the verbal report on the Reduction of the Need for Antimicrobials in Food Producing Animals (RONAFA) meeting to the September 2016 CVMP meeting.
- The Committee deferred the verbal report on the 2nd Joint Inter-agency Antimicrobial Consumption and Resistance Analysis (JIACRA) meetings to the September 2016 CVMP meeting.

8.4 Pharmacovigilance

8.5 Other issues

Information on other critical issues related to centralised procedures cannot be released at the present time as it is deemed to contain commercially confidential information.

- The Committee deferred the verbal report on the simulation exercise for the incident management plan for medicines for veterinary use to the September 2016 CVMP meeting.

- The Committee endorsed the presentation to be given by the CVMP representative for the Horizon 2020 project PARAGONE Vaccines for animal parasites consortium meeting to be held on 29-30 August 2016 in Ghent, Belgium.

9. AVAILABILITY OF MEDICINES AND MUMS CLASSIFICATION

Information relating to availability of medicines cannot be released at the present time as it is deemed to be commercially confidential.

10. PROCEDURAL AND REGULATORY MATTERS

10.1 Eligibility and appointment of rapporteurs, co-rapporteurs and peer reviewers

Information relating to notification of intent for new MRL applications and notification of intent and eligibility requests for Community marketing authorisations cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee agreed to the transfer of all rapporteur- and co-rapporteurships and peer reviewer responsibilities from D. Murphy to J. G. Beechinor.

10.2 Regulatory matters

Information relating to certain regulatory issues cannot be released at the present time as it is deemed to be commercially confidential.

- The Committee discussed the revised QRD veterinary template.
- The Committee received a verbal update on the Notice to Applicants meeting held on 7 June 2016.

11. CO-ORDINATION GROUP FOR MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

- The Committee received a verbal report from the chair of CMDv on the meetings held on 19-20 May and 16-17 June 2016, and noted the draft minutes of the meeting held on 16-17 June 2016 as well as the draft agenda of the meeting held on 14-15 July 2016.

12. ORGANISATIONAL AND STRATEGIC MATTERS

- The Committee endorsed the revision of the procedure for the nomination and appointment of co-opted members in CHMP, CVMP and HMPC (EMA/4789/2007-rev.2).
- The Committee elected H. Jukes as vice-chair of CVMP for a 3-year term.
- The Committee deferred the discussion on the results of the survey concerning the appointment of rapporteurs for CVMP procedures.
- The Committee discussed the appointment of CVMP co-opted members at the October 2016 meeting and the expertise necessary for CVMP to accomplish its mandate.
- The Committee deferred the discussion on the revised VNeeS format requirements guideline which had come into force on 1 July 2016, and the revision of the exceptions to the VNeeS format.
- The Committee discussed the summary and conclusions of the CVMP/CMDv Presidency meeting held on 27-28 June 2016 in the Netherlands and noted the final agenda of the meeting.

- The Committee discussed the EMA Annual report 2015 on the performance of the Agency's scientific procedures: Key Performance Indicators (KPIs) for medicinal products for human and veterinary use.
- The Committee received a verbal report on the Strategic Planning Group meeting held on 12 July 2016, and noted the agenda of the meeting and the minutes of the meeting held on 16 March 2016.
- The Committee deferred the discussion on the revision of the dossier submission requirements document to commence following the July 2016 CVMP plenary meeting to the September 2016 CVMP meeting.
- The Committee noted the Council Decision of 29 May 2016 on the appointment of four Management Board members, including a veterinary representative.
- The Committee postponed the update on veterinary curriculum of the EU Network Training Centre project.
- The Committee was informed of potential issues or procedures that would require CVMP decision via written procedure during August 2016.

13. LEGISLATION

- The Committee deferred the update on the development of CVMP recommendations for methodological principles for the risk assessment and risk management recommendations (*"Volume 8"*) to the September 2016 CVMP meeting.

14. ANY OTHER BUSINESS

- Upon the completion of the July 2016 CVMP meeting, the draft press release was circulated for members to provide any comments within 24 hours.

ANNEX I - List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the July 2016 meeting

Country	CVMP Member	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
CHAIR	**David Murphy**	**Full involvement**	
AT	Barbara Zemann	Cannot act as rapporteur or peer reviewer for:	• 5.6 Ingelvac CircoFLEX & Semintra
BE	Bruno Urbain	Full involvement	
BG	Emil Kozhuharov	Full involvement	
DE	Cornelia Ibrahim	Full involvement	
EE	Toomas Tiirats	Full involvement	
EL	Ioannis Malemis	Full involvement	
ES	Cristina Muñoz Madero	Full involvement	
FR	Jean-Claude Rouby	Full involvement	
HU	Gábor Kulcsár	Full involvement	
IT	Paolo Pasquali	Full involvement	
LU	Marc Schmit	Full involvement	
LV	Zanda Auce	Full involvement	
MT	Stephen Spiteri	Full involvement	
NL	G. Johan Schefferlie	Full involvement	
PL	Anna Wachnik-Święcicka	Full involvement	
RO	Lollita Taban	Full involvement	
SE	Eva Lander Persson	Full involvement	
SI	Stanko Srčič	Cannot act as rapporteur or peer reviewer for:	• 4.3 Gentamicin (EMEA/V/A/117)
UK	Helen Jukes	Full involvement	
Co-opted	Rory Breathnach	Full involvement	
Co-opted	Christian Friis	Full involvement	
Co-opted	Wilhelm Schlumbohm	Full involvement	
Co-opted	Jason Weeks	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
BE	Frédéric Klein	Full involvement	
DE	Esther Werner	Full involvement	
DK	Merete Blixenkrone-Møller	Full involvement	
FR	Sylvie Louet	Full involvement	
HR	Frane Božić	Full involvement	
IE	J. Gabriel Beechinor	Full involvement	
PL	Ewa Augustynowicz	Full involvement	
PT	Maria Azevedo Mendes	Full involvement	
SE	Frida Hasslung Wikström	Full involvement	

Country	CVMP Alternate	Outcome restriction following evaluation of e-DoI for the meeting	Topics on current agenda for which restriction applies
UK	Noemi Garcia del Blanco	Full involvement	
NO	Tonje Høy	Full involvement	

Country	CVMP Expert*	Outcome restriction following evaluation of the e-DoI for the meeting	Topics on current agenda for which restriction applies
* Experts were only evaluated against the topics they have been invited to talk about.			
DE	Katrin Kirsch *(remotely)*	Full involvement	
DE	Inke Reimer *(remotely)*	Full involvement	
DK	John Jensen	Full involvement	
ES	Alberto de Prado Lopez *(remotely)*	Full involvement	
ES	Carmen Fernandez Felipe *(remotely)*	Full involvement	
ES	Maria Jose Ferrer *(remotely)*	Full involvement	
ES	Patricia Vera Luque *(remotely)*	Full involvement	
FI	Kristina Lehmann *(remotely)*	Full involvement	
FI	Martti Nevalainen *(remotely)*	Full involvement	
FR	Damien Bouchard *(remotely)*	Full involvement	
FR	Jean Christophe Faucon *(remotely)*	Full involvement	
FR	Martine Redureau	Full involvement	
IT	Maria Tollis *(remotely)*	Full involvement	
NL	Willie Peijnenburg	Full involvement	
SE	Susanne Stenlund *(remotely)*	Full involvement	
UK	Rutendo Manyarara *(remotely)*	Full involvement	
UK	Jean-Paul Schmidt *(remotely)*	Full involvement	

CVMP working parties and CMDv	Chair
ADVENT	Jean-Claude Rouby
AWP	Helen Jukes
CMDv	Gavin Hall
ERAWP	Jason Weeks

CVMP working parties and CMDv	Chair
EWP-V	Gesine Hahn
IWP	Esther Werner
PhVWP-V	Peter Ekström *(remotely)*
QWP	--
SAWP-V	Rory Breathnach
SWP-V	Eva Lander Persson

Observer from the European Commission	
Present	

European Medicines Agency support
Meeting run with relevant support from the EMA staff